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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,778

03/19/2004

Richard A. Gross

14690.011USA

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7590

08/28/2007

LAURENCE P. COLTON

1201 WEST PEACHTREE STREET, NW

14TH FLOOR

ATLANTA, GA 30309-3488

EXAMINER

ISSAC, ROY P

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

08/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,778	GROSS ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 13-27 and 32-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims priority under 35 U.S.C § 119(e) from the provisional application No. 60/456,208 filed 20 March 2003.

Election/Restrictions

Applicant's election of Group II, claims 1-12 and 28-31 in the reply filed on 05/07/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Because these inventions are independent or distinct for the reasons set forth in the restriction requirement mailed 4/10/2007 and because the response was made without pointing out any supposed errors, the requirement is deemed proper and is therefore made FINAL.

Claims 13-27 and 32-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Therefore, claims 1-12 and 28-31 are examined on the merits herein.

Claim Objections

Claims 1-12 and 28-31 are objected to because of the following informalities. The preamble of the claims state that the claims are directed to a method of producing sophorolipids while the claim contains elements that are both a manufacture as well as a process. One may only patent something that is

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a machine, manufacture, composition of matter or a process. See, e.g., Alappat, 33 F.3d at 1542, 31 USPQ2d at 1556; Warmerdam, 33 F.3d at 1358, 31 USPQ2d at 1757 (Fed. Cir. 1994). The claims herein are directed to two statutory classes of subject matter and thus does not fall into either of the categories. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7, 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recited the term "based" to modify recited names of compounds. The term "based" does not give any information as to the structure, properties and nature of the compounds covered by the claims. The recitation is not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "based" of compounds herein. One of ordinary skill in the art would clearly recognize that compounds that are based on the recited compounds would read on any those compounds having any widely varying groups that possibly substitute the compounds.

Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g., physical, chemical, physiological effects and

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functions. Thus, it is unclear and indefinite as to the "based" of compounds herein encompassed thereby.

Claims 1-12 and 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims recite a method of producing sophorolipids and another process for "utilizing" sophorolipids produced. This step is regarded as a "use" step because it provides for the use of the claimed fraction as an antifungal agent. However, the claim does not set forth any steps for using the fraction. Thus it is unclear what method/process applicant is intending to claim. A claim is indefinite where it merely recites a use without any active steps delimiting how this use is actually practiced. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-12 and 28-31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 and 28-31 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-9 of copending Application No. 11/020,683. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6 and 9 of the '683 application is drawn to a method of making sophorolipids via fermentation of *C. Bombicola* based on the same sophorolipid esters claimed in the instant application. The recitation of anti-viral and anti-fungal properties are intended use of the same compounds and does further limit the compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1-12 and 28-31 are provisionally rejected on the ground of nonstatutory double patenting over claims 4-7, 10-14, and 16-21 of copending Application No. 10/807,961. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-7, 10-14, and 16-21 of the '961 application is drawn to a method of making sophorolipids via fermentation of *C. Bombicola* based on the same sophorolipid esters claimed in the instant application. The recitation of anti-viral and anti-sepsis properties are intended use of the same compounds and does further limit the compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bisht et. al. (J. Org. Chem. 1999, 64, 780-789; PTO-892).

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Bisht et. al. discloses the synthesis of sophorolipids by fermentation of *C. bombicola* which produces lactone and open chain forms of sophorolipids. (Figure 1, Page 780; Page 781, Column 2, Paragraphs 3-4). The recitations, "utilizing the natural mixture as a spermicidal and/or antiviral agent", "utilizing the lactonic fraction as a spermicidal and/or antiviral agent" and "utilizing the non-lactonic fraction as a spermicidal and/or antiviral agent" are considered intended use since no definite physical steps are recited.

No Claim is allowed.

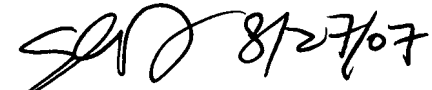
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac
Patent Examiner
Art Unit 1623


S. Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623